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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,910	12/28/2001	Hiroshi Nagasawa	NAGASAWA=6	2855

1444 7590 06/24/2002
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EXAMINER

FORMAN, BETTY J

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 06/24/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/028,910	NAGASAWA, HIROSHI
	Examiner BJ Forman	Art Unit 1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 April 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-5 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Restrictions

1. Applicant's election with traverse of Group I, Claims 1-3, filed 15 April 2002 in Paper No. 4 is acknowledged. Upon further consideration by the examiner and in view of the art, Groups I and II have been rejoined. Claims 1-5 are under consideration and discussed below.

Claim Objections

2. Claim 3 is objected to in line 2, for the recitation "into a bundled of capillaries" because the syntax is incorrect. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-3 are indefinite in Claim 1 for the recitation "an affinity detecting/analytical chip" because it is unclear whether the chip is an "affinity detecting" and an "affinity analytical". It is suggested that Claim 1 be amended to clarify.

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b. Claims 1-3 are indefinite in Claim 1 for the recitation “probe molecules causing different specific binding reactions” because “causing” is functional language, but it is unclear what structural limitations the functional language imposes on the chip. It is suggested that Claim 1 be amended to define the structural components of the chip e.g. replace “causing” with “having” and replace “reactions” with “activity” (page 4, line 33-page 5, line 24).

c. Claims 2 and 3 are indefinite in Claim 2 for the recitation “the probe molecules are DNA’s, RNA’s.....or functional site polypeptide chains thereof.” because the species of probe molecules are listed in both the alternative “or” and the inclusive “and”. Therefore it is unclear whether the chip comprises one or more than one species of probe molecules. It is suggested that Claim 2 be amended to clearly define the probe molecules (see MPEP 2173.05(h)).

d. Claim 3 is indefinite because the claim is drawn to a method for producing a chip but the claim does not recite method steps of chip production. Method claims need not recite all operating details but should at least recite positive, active steps so that the claims will set out and circumscribe a particular area with a reasonable degree of precision and particularity and make clear what subject matter that claims encompass as well as make clear the subject matter from which others would be precluded, *Ex parte Erlich*, 3 USPQ2d 1011 at 6.

e. Claim 4 is indefinite for the recitation “probe molecules causing different specific binding reactions to cause specific binding reactions” because it is unclear whether the recitation is a method step of causing different reactions or causing specific reactions. It is suggested that Claim 4 be amended to clarify e.g. in line 4, replace “causing” with “having” and inline 5, replace the first “reactions” with “activity” (page 4, line 33-page 5, line 24).

f. Claim 4 is indefinite for the recitation “applying light from one end of the capillary” because it is unclear whether the light is applied “from” one end to “into” one end so as to be observed exiting form the opposite end. It is suggested that Claim 4 be amended to clarify e.g. replace “from” with “into” or “at” (Fig. 10).

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g. Claim 4 is indefinite for the recitation “observing light exiting from an opposite end surface” because it is unclear whether the “surface” is an inner surface, an outer surface or the end of the capillary. It is suggested that Claim 4 be amended to clarify as defined or illustrated in the specification.

h. Claim 4 is indefinite because the claim is drawn to a method of detection, but the method does not recite method steps of detection. It is suggested that Claim 4 be amended to clarify e.g. in line 12, replace “presence” with “detection”.

i. Claim 5 is indefinite for the recitation “an affinity detecting/analytical chip” because it is unclear whether the chip is an “affinity detecting” and an “affinity analytical”. It is suggested that Claim 5 be amended to clarify.

j. Claim 5 is indefinite for the recitation “the analyte-bound affinity detecting/analytical chip” because the recitation lacks proper antecedent basis in the Claim. It is suggested that Claim 5 be amended to provide proper antecedent basis e.g. delete “the analyte-bound”.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international

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application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

6. Claims 1, 2, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Dehlinger (U.S. Patent No. 5,763,263, issued 9 June 1998).

Regarding Claim 1, Dehlinger discloses an affinity detecting/analytical chip comprising a plurality of capillaries bundled together said capillaries having fixed to an inner surface thereof probe molecules having different specific binding reactivity (Column 3, lines 54-64 and Column 8, lines 17-33).

Regarding Claim 2, Dehlinger discloses the chip wherein the probe molecules are DNAs, RNAs, oligonucleotides, proteins, peptides, antigen, epitope (Column 6, lines 51-59).

Regarding Claim 4, Dehlinger discloses a detection method comprising flowing molecules as a sample into a bundle of capillaries having fixed to an inner surface thereof probe molecules having different specific binding reactivity, thereby binding the sample molecules to the inner surface of the capillaries; applying light from one end of the capillary bundle; and observing light exiting from an opposite end of the capillary bundle thereby examining the capillaries for the presence of binding (Column 18, lines 5-45 and Fig. 11A and 11B).

Regarding Claim 5, Dehlinger discloses a reaction product detection system comprising a binding device for binding an analyte to an affinity detecting/analytical chip comprising a plurality of capillaries precisely positioned, bundled together by binding means and further resin molded (Column 8, lines 17-33), each of said capillaries having probe molecules fixed to an inner surface thereof; a light absorption observation device comprising a module housing portion for accommodating the analyte-bound affinity detecting/analytical chip, a light emitting portion provided ahead of the module housing portion and an observation unit provided behind the module housing portion; and a data processing device connected to the light absorption

observation device i.e. photodiode array, photodiode detector elements and position detection via optical input from each photodiode (Column 18, lines 29-39 and Fig 11 B).

7. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Landgren et al (WO 96/17246, published 6 June 1996).

Regarding Claim 1, Landgren et al disclose an affinity detecting/analytical chip comprising a plurality of capillaries bundled together said capillaries having fixed to an inner surface thereof probe molecules having different specific binding reactivity (Claims 1 and 2).

Regarding Claim 2, Landgren et al disclose the chip wherein the probe molecules are DNAs, RNAs, oligonucleotides, proteins, peptides, antibodies (Claim 9).

Regarding Claim 3, Landgren et al disclose a method for producing the chip of Claims 1 and 2 comprising bundling different capillaries while precisely positioning the capillaries, said capillaries having the probe molecule fixed to the inner surface beforehand (Claim 11).

8. Claim 5 is rejected under 35 U.S.C. 102(e) as being anticipated by Schellenberger et al (U.S. Patent No. 6,306,578, filed 17 March 2000).

Regarding Claim 5, Schellenberger et al disclose a reaction product detection system comprising a binding device for binding an analyte to an affinity detecting/analytical chip comprising a plurality of capillaries precisely positioned, bundled together by binding means

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and further resin molded, each of said capillaries having probe molecules fixed to an inner surface thereof; a light absorption observation device comprising a module housing portion for accommodating the analyte-bound affinity detecting/analytical chip, a light emitting portion provided ahead of the module housing portion and an observation unit provided behind the module housing portion; and a data processing device connected to the light absorption observation device (Column 7, lines 41-60 and Fig 4).

Conclusion

9. No claim is allowed.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
June 20, 2002